REMARKS

The claims in the application are 21-27, 29-30, 35-36,38, 39, 49,51, 54-56 and 60-62. By way of this amendment Claims 31-34, 37, 50, 52-53 and 57-59 have been cancelled, Claim 21 has been amended to include minerals, claim 49 has been amended to recite the molecular weight must be less than or equal to 100,000 daltons and claims 60-62 have been added. Support for this amendment can be found throughout the specification, in particular at pages 5-9. Since the specification states that the compositions can contain unhydrolyzed sericin as well as hydrolyzed sericin, and since the molecular weight of unhydrolyzed sericin is 100,000 daltons, the specification therefore teaches compositions comprising unhydrolyzed 100,000 daltons sericin protein and hydrolyzed fragments of the sericin protein that by definition must be less than less than 100,000 daltons. Support for the amendment of Claim 21 and new claim 60 can be found throughout the specification and in particular at pages 7-9 and Claim 6 as originally filed. Support for claims 61-62 can be found throughout the specification and at pages 18-21. No new matter has been added.

Favorable reconsideration of the application as amended is respectfully requested.

In the Office Action, the Examiner stated that the Specification lacks a separate section of "BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S)" for figures 1-4. The Applicants respectfully direct the Examiner's attention to paragraph [0060], page 21, which provides the requisite description of the figures set apart as a properly title section of the application. Therefore,

the Applicants respectfully assert that the specification already contains the requested section and no additional information is required.

In the Office Action, claim 51 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for including the phrase "a single protein." By way of this amendment, claim 51 has been amended to remove any reference to a single protein. In view of the foregoing, the rejection of claim 51 should be reconsidered and withdrawn.

Claims 49 and 50-53 have been rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner stated that the limitation " an average molecular weight range between 20,000 and 100,000" in claim 49 and 50 and also the limitation "at least 20,000" in claims 52-53 is not supported by the specification. Claims 50 and 52-53 have been cancelled and the rejection of these claims is now moot. Claim 49 has been amended to recite "average molecular weight of less than or equal to 100,000 daltons." As stated above, since the specification states at page 9 that the molecular weight of the unhydrolyzed sericin protein is 100,000 daltons and the composition of the present invention may contain unhydrolyzed sericin protein, hydrolyzed sericin protein (which by definition must weight less than the unhydrolyzed protein) and mixtures thereof, the specification provides written support for claim 49 as amended. In view of the foregoing, the rejection of claim 49 under 35 U.S.C. § 112, first paragraph, should be reconsidered and withdrawn.

At page 5, first full paragraph of the Office Action, the Examiner states that the limitation "at least 20,000" is in base claims 21 and 31. Although the

Examiner has not rejected these claims in the current Office Action, in an effort to keep the record clear of misstatements, it is noted that the amendment filed October 21, 2005 deleted this phrase from Claim 21; as presently presented claim 21 does not include this limitation. Claim 31 has been cancelled by this amendment.

In the Office Action, Claims 21-27, 29-31, 34, 36-39, 49-59 are rejected under 35 U.S.C. § 102 (e) as being anticipated by US Patent No. 6,165, 982 (Yamada et al.).

As is well settled, anticipation requires "identity of invention," *Glaverbel Societe Anonynie v. Northlake Mktg. & Supply*, 33 USPQ 2d 1496, 33 USPQ 2d 1496, 1498 (Fed. Cir. 1995). Each and every element recited in a claim must be found in a single prior art reference and arranged as in the claim. *In re Marshall*, 198 USPQ 344, 346 (CCPA 1978); *Lindenmann Maschinenfabrik GmbH v. American Hoist and Denich Co.* 221 USPQ 481, 485 (Fed. Cir. 1984). There must be no differences between what is claimed and what is disclosed in the applied reference. *In Re Kalm*, 154 USPQ 10, 12 (CCPA 1967), *Scripps v. Genentech Inc.*, 18 USPQ 2d 1001, 1010 (Fed. Cir. 1991).

As stated above, Claim 21 has been amended to require a mineral mix as part of the functional oral preparation. As amended, the functional oral reparation of Claim 21 comprises at least one ingredient selected from the group consisting of water-soluble sericin powder extracted from silk worm cocoons or raw silk with a purity of 90% or higher, its hydrolyzed powder product with a purity of 90% or higher and mixtures thereof, and a mineral mix, in an effective amount to prevent colon cancer in a dosage form oral preparation.

Claim 60 depends from Claim 21 and provides a listing of minerals that can be in the mineral mix of Claim 21.

Yamada et al. does not teach or suggest a functional oral preparation containing a mineral mix as required by the claims as amended. Since Yamada et al. does not teach each and every element recited in the claims, the Applicants respectfully request that the rejection of Claims 21-27, 29-31, 34, 36-39, 49-59 under 35 U.S.C. § 102(e) be reconsidered and withdrawn.

In the Office Action, Claims 21-27, 29-32, 34-39, and 49-59 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for making powder sericin with the molecular weight greater than 100 kDa with 90% purity or higher, the Examiner alleges that the specification does not reasonably provide enablement for making sericin powder with an average weigh of 20KDa. (See Office Action, bottom page 7- page 8).

The Applicants respectfully note that Claims 21-27, 29-30, 35-36,38-39 and 49, 50, and -59 have been amended so that the limitation "present in an average molecular weight of at least 20,000" was deleted form claim 21 and 31 in the amendment after final filed with the RCE mailed October 21, 2005. In view of the foregoing, the rejection of Claims 21-27, 29-32, and 34-39 is moot and should be withdrawn.

As for Claims 49-59, claim 49 has been amended to depend from Claim 21, and the molecular weight was redefined to have an average molecular of less than or equal to 100,000 daltons. As stated above, since the specification teaches that oral preparations of the present invention can contain unhydrolyzed sericin as well as hydrolyzed sericin, and since the molecular weight of

unhydrolyzed sericin is 100,000 daltons, the specification therefore teaches oral composition comprising unhydrolyzed 100,000 daltons sericin protein and hydrolyzed fragments of the sericin protein that by definition must be less than less than 100,000 daltons. As described in the preparation Example 2 of the present invention, the unhydrolyzed sericin powder of Example 1 is subjected to treatment in a 0.2% solution of sodium bicarbonate at a pH of 11-12 at 95 degrees Celsius for two hours. The resultant extract was filtered and the hydrolyzed sericin product was obtained. Since this procedure does not utilize enzyme degradation, but utilization chemical (basic) and heat catalysis of the sericin protein, the sizes of the fragments produced would not be expected to be of a specific size and weight by rather of various sizes. Therefore, the full range of fragments can be obtained, each weighing less than the full sericin protein (100kDa).

In addition, in making the rejection the Examiner states that Teramoto et al teaches that only three kinds of sericin exists, one greater than 250kDa, one about 180kDa, and one about 100kDa. (See Office Action, page 8 last two paragraphs). However, the Applicants respectfully direct the Examiner's attention to the last portion of the same column of the cited reference where it states that when the sericin solution containing these three fragments "was autoclaved at 121 degrees celsius for 20 min, the protein bands of the main sericin components disappeared (Fig. 1, Lane 3)" (Teramoto et al., p.845, col. 2 last paragraph). Column 3 of the SDS-page gel shows a "smear" starting at about the 250kDa molecular weight line to below 50 KDa molecular weight line, indicating the presence of hydrolyzed fragments having molecular weights of less

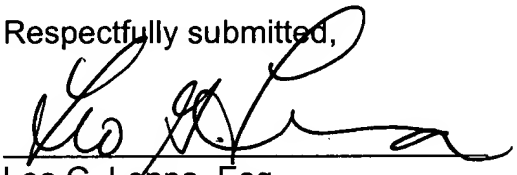
than 100KDa as claimed.

In view of the foregoing, the Applicants respectfully request that the rejection of claims 21-27, 29-32, 34-39, and 49-59 rejected under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

Therefore, in view of the forgoing amendment, and accompanying remarks, it is respectfully submitted all claims pending herein are in condition for allowance. Please contact the undersigned attorney should there be any questions.

Early favorable action is earnestly solicited.

Respectfully submitted,



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